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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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Chm

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

04.05.2004

Applicant's or agent's file reference
X-15430

IMPORTANT NOTIFICATION

International application No.
PCT/US 03/00027 ✓

International filing date (day/month/year)
16.01.2003

Priority date (day/month/year)
28.01.2002

Applicant
ELI LILLY AND COMPANY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference X-15430	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US 03/00027	International filing date (<i>day/month/year</i>) 16.01.2003	Priority date (<i>day/month/year</i>) 28.01.2002
International Patent Classification (IPC) or both national classification and IPC B65D81/26		
Applicant ELI LILLY AND COMPANY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 21.08.2003	Date of completion of this report 04.05.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Sedy, R Telephone No. +31 70 340-2978 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/US 03/00027**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-5 as originally filed

Claims, Numbers

1-7 filed with telefax on 10.02.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/US 03/00027**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-7
	No: Claims	
Inventive step (IS)	Yes: Claims	1-7
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-7
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

US-A-5194315 which is considered to represent the nearest **prior art** discloses (see e.g. column 2, lines 55-65) a case (5) for storing a portable medication delivery device having

a first part (5a) having an exterior surface and an interior surface;

a second part (5b) having an exterior surface and an interior surface;

the first and second parts (5a, 5b) are movable relative to each other between a case opening arrangement and a case closing arrangement, in which when in the case closing arrangement the interior surface of the first part (5a) and the interior surface of the second part (5b) are in facing relationship that defines an internal volume therebetween;

means on at least one of the interior surfaces for storing the portable medication delivery device within the internal volume; and

a desiccant (2,15,16) held by the first part and in air flow communication with the internal volume for limiting moisture buildup on the portable medication delivery device.

The technical problem to be solved by the present invention is therefore to provide a secure and protected installation of a desiccant inside the portable case.

The solution as specified in claim 1 solves this problem by installing the desiccant within a storage space between the interior surface of the first part and the exterior surface of the first part.

This solution is not obvious insofar as the first part has to be hollowed out and has to be foreseen with air flow communication means.

According to US-A-5194315 a desiccant packing is fixed by staples to the inside surface of the upper flap part of the case. Thus, the desiccant packing is unprotected and could be damaged during loading or unloading of the case.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US03/00027

Dependent claims 2 to 7 specify advantageous embodiments of the subject-matter of claim 1.

Consequently, the subject-matter of claim 1 to 7 meets the requirements of Articles 33(2) and (2) PCT.

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CLAIMS

I CLAIM:

1. A case for storing a portable medication delivery device, comprising:
a first part having an exterior surface and an interior surface;
5 a second part having an exterior surface and an interior surface;
said first and second parts movable relative to each other between a case opening
arrangement and a case closing arrangement, wherein when in said case closing
arrangement said interior surface of said first part and said interior surface of said second
part are in a facing relationship that defines an internal volume therebetween;
10 means on at least one of said interior surfaces for storing the portable medication
delivery device within the internal volume; and
characterized in that a desiccant is held by said first part and in air flow
communication with said internal volume for limiting moisture buildup on the portable
medication delivery device, wherein said desiccant is held within a storage space between
15 said interior surface of said first part and said exterior surface of said first part.
2. The case of claim 1 wherein said interior surface defines at least one
opening therethrough to facilitate air flow communication between said storage space and
said internal volume.
3. The case of claim 2 wherein said at least one opening comprises a plurality
20 of openings.
4. The case of claim 1 wherein said first and second parts are hingedly
connected in a clamshell configuration to be pivotably movable between the case opening
and case closing arrangements.
5. The case of claim 1 wherein said storing means comprises a recess of said
25 interior surface of said second part in which at least partially insertably fits the portable
medication delivery device.
6. The case of claim 1 wherein said first part comprises a shell and an insert
attached thereto, wherein said shell forms said exterior surface of said first part and said
insert forms said interior surface of said first part, and wherein said storage space is
30 formed between said shell and said insert.

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7. The case of claim 6 wherein said insert defines at least one opening therethrough to facilitate air flow communication between said storage space and said internal volume.

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AMENDED SHEET